UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF JOHN MIKLOS, M.D.

Plaintiffs lead their opposition brief with petty criticisms that have no substantive bearing on the admissibility of Dr. Miklos's testimony. For instance, Plaintiffs' criticisms of Defendants' citation to Dr. Miklos's prior deposition testimony in other mesh litigation is disingenuous. Both Plaintiffs and Defendants in this MDL have cited to and rely on prior deposition testimony in both supporting and attacking the opinions of designated experts. Indeed, the parties have been encouraged to be efficient and non-repetitive in conducting depositions.

Dr. Miklos was deposed on his TVT Secur opinions in the *Garcia* litigation just last year. His MDL report and criticisms are substantially similar to his prior opinions. Accordingly, Defendants agreed to conduct only a one-and-a- half hour deposition of Dr. Miklos regarding his TVT Secur opinions in this MDL. The deposition was conducted less than two weeks prior to the *Daubert* motion deadlines. Use of Dr. Miklos's prior *Garcia* testimony in examining his MDL opinions is consistent with the direction provided by this Court and increases the efficiency for all parties.

Plaintiffs also mock Defendants for challenging Dr. Miklos's ability to opine regarding laser-cut mesh fraying and the TVT Secur's Ethisorb fixation method, when (according to Plaintiffs) these "defects" are not mentioned anywhere in Dr. Miklos's MDL Report. Yet, Dr. Miklos's report cites numerous Ethicon documents and other literature regarding laser-cut versus mechanically-cut mesh. Miklos Rep. at 53-54, 76, 78, 184 (e.g., citing "Mechanical vs. 'Machine'-cut Mesh" - Powerpoint on mechanical vs. ultra-sonic/laser cut mesh; Project TVT Laser Cut Mesh Design History File; Particle Loss on TVT – "Emails discussing TVT particle loss and Performance Evaluation Test Report evaluating the amount of particle loss in laser cut and mechanical cut TVT Prolene mesh"). Moreover, his report expressly refers to "design flaws" of the TVT Secur including "fixation tips not staying in place." Miklos Rep. at 14. The fixation tips are the Ethisorb tips he discussed in his *Garcia* deposition. 2/6/15 Dep. at 296:21 - 298:3 (discussing the Ethisorb caps and Dr. Miklos's concern that they do not "fixate appropriately"). Therefor it is appropriate for Defendants to challenge those opinions in the present litigation – despite the fact that Dr. Miklos's MDL report did not expressly use the word "Ethisorb." Significantly, Plaintiffs now represent that these opinions are "not even proffered" in this MDL. Pltfs' Opp. p.4 & n.2. Accordingly, relying on this representation, Dr. Miklos should be precluded from testifying regarding Ethisorb fixation issues as well and potential differences between mechanical and laser-cut mesh.

In addition, for the reasons stated in Defendants' opening brief, as well as the arguments set forth below, Dr. Miklos's testimony should be limited to his clinical expertise, and opinions that are reliably supported by sound methodology.

LEGAL ARGUMENT

I. Dr. Miklos's opinion that the TVT Secur is defectively designed is unreliable.

As set forth above, Plaintiffs' primary response to Defendants' challenges to Dr. Miklos's design defect opinions is that Dr. Miklos either is not offering the opinion in this MDL or that he is an extremely qualified surgeon who can thus opine on the design of the TVT Secur without applying sound methodology. Pltfs' Opp. at 4-6.

Dr. Miklos's criticisms of TVT Secur's alleged intolerable failure rates due to purported defects such as the insertion and retraction mechanism, as well as the Ethisorb fixation mechanism are unsupported by any reliable scientific evidence. Miklos Rep. at 8-9, 13-14. To the contrary, one TVT Secur study he was directly involved in concluded that the TVT Secur was "as efficacious as its predecessors." 2/6/15 Dep. at 184:9-18 & Ex. 18 thereto (attached as Ex. D). In his deposition, Dr. Miklos reluctantly acknowledged that there are several other randomized clinical trials (which are the highest level of data on TVT Secur) that show that the device is effective. (Exhibit E to Motion. 4/8/16 Dep. at 28:9-29:3). For example, he acknowledged several studies with efficacy rates of 80-100%, and he acknowledged other randomized clinic trials in which the TVT Secur was demonstrated to be as efficacious as TVT or TVT-O, which Dr. Miklos believes to be effective and safe. (4/8/16 Dep. at 28:9-29:3; *see also* 2/6/15 Dep. at 178:9-179:4; 184:9-18; 342:21-23).

Indeed, Dr. Miklos admitted that a study conducted by Mauro Cervigni and Bernasconi, 24 months out, indicated a 89.5 percent cure rate with the TVT Secur. *See* Bernasconi, Franceso, et al., *TVT Secur System: final results of a prospective, observational, multicentric study*, Int. Urogynecol. J. (2012) 23:93-98 (also noting that familiarity with technique brought significantly

higher success rates, and that TVT Secur is "safe, effective and versatile")(attached as Ex. A hereto). Instead of explaining why the study might be flawed, or pointing out some other factor that would indicate the result is unreliable, Dr. Miklos admits "Okay, that's a decent study. I know Mauro Cervigni, I've operated with him in Rome. I like him, he's a good guy, he's pretty honest. Not a bad study." (4/8/16 Dep. at 28:9-29:3). Similarly, he acknowledged the Neuman study that demonstrated a 91 percent cure rate at three years out. *Id*; Menahem Neuman, MD, et al., *Transobturator vs Single-Incision Suburethral Mini-slings for Treatment of Female Stress Urinary Incontinence: Early Postoperative Pain and 3-Year Follow-up*, J. Minimally Invasive Gyn. V.18 (Dec. 2011) (reporting cure rates of 86.9% in the TVT-O group and 90.9% in the TVT Secur group, and concluding "Both procedures were effective, with few adverse effects. In sexually inactive patients, the TVT Secur procedure may be preferable because thigh and vaginal pain is largely averted with this procedure.")(attached as Ex. B hereto). He offered no criticisms or basis for rejecting these results.

The only study he criticized was a multi-prospective randomized trial of three different studies by Dr. Lou, who Dr. Miklos indicated reported a 100 percent cure rate, a 99.5 percent cure rate, and a 98.5 percent cure rate. (4/8/16 Dep. at 28:9-29:3).[1] Dr. Miklos identified no flaw in the study or any substantive indication of unreliability, other than it gives him "a little angst when anybody has a 100 percent cure rate on an operation 12 months out of surgery." He went on to acknowledge, but not criticize, two additional studies reporting high success rates:

[1]. Although it is somewhat unclear, it appears Dr. Miklos was referring to De-Yi Luo, et al., *Different sling procedures for stress urinary incontinence: A lesson from 453 patients* , Kaohsiung Journal of Medical Sciences (2013) xx, 1e7. (attached as Ex. C hereto) As reported by Dr. Lou, "The cure and improvement rates were similar among the treatment groups: 97.14% (102/105) in TVT, 100% (243/243) in TVTO, 98.89% (89/90) in [Secur]TVT-S, and 100% (15/15) in PVS. Only minor complications were experienced by the patients. In conclusion, each MUS procedure was observed to be safe and effective in different subpopulations of patients, and the results suggest that appropriate patient selection is crucial for the success of each MUS procedure." Dr. Lou's conclusions clearly indicate a comparable success (and failure) rate between TVT Secur and other mesh slings. Dr. Miklos has failed to provide a scientifically sound basis for rejecting this conclusion.

> So we still have a couple other studies in the 80 to 90 percent range and that would be -- that I'm aware of and that is Kim from Korea, who sits out at 88 and 89 percent using the UNH technique and then you also have Kandawalla, who has an 84 percent cure rate at 14 months out.

4/8/16 Dep. at 29:7-11. *See* Salil Khandwala, et al., *Experience with TVT-SECUR sling for stress urinary incontinence: a 141-case analysis*, Int Urogynecol J (2010) 21:767–772 (attached as Ex. D hereto)

Instead of providing a basis for the rejection of these studies, Dr. Miklos acknowledged that it is the surgeon's skill set and technique that are the most important factors in the use of a device, and not the device (or any alleged defect) itself. (4/8/16 Dep. at 11:7-12; *see* 2/6/15 at 147:12-148:3). He acknowledged that TVT Secur works in various surgeons' hands. (2/6/15 Dep. at 195:8-16; 290:23-291:). Dr. Miklos's own testimony belies his opinion that TVT Secur is defective, as he fails to provide a basis for rejecting studies contrary to his opinion, and fails to rule out surgeon skill and technique as the reason why some studies had lower efficacy.

II. Dr. Miklos's opinion that there were safer alternative products must be supported by reliable evidence.

In opposition to Defendants' argument that Dr. Miklos's testimony regarding safer alternative products is unreliable, Plaintiffs essentially argue that he does not have to provide any scientifically valid evidence establishing the safety or the efficacy of the suggested alternative. Pltfs' Opp. at 7. Plaintiffs' position is absurd. *Daubert* does not have an exception to expert testimony related to alternative designs; these opinions must meet the reliability standards that all expert testimony must satisfy.

To prove design defect, the Third Restatement requires a plaintiff to demonstrate the existence of a reasonable alternative product design. Comment d to §2 of the Third Restatement defines reasonable alternative product design in terms of the "risk-utility balancing test." The test

is "whether a reasonable alternative design would, at a reasonable cost, have reduced the foreseeable risk of harm posed by the product and, if so, whether the omission of the alternative design by the seller . . . rendered the product not reasonably safe." Most jurisdictions apply the same requirement, or at least make the existence of a safer alternative design a relevant factor to determining whether a product was indeed defective.

If an expert cannot reliably establish that a proffered alternative was both safer and effective, then the testimony is unreliable and unhelpful (even confusing) to a jury. Dr. Miklos has failed to link his conclusions to the analysis, if any, that he performed to determine that his proposed alternatives (the retropubic and inside-out trans obturator slings) are indeed more effective. His theory relies heavily upon his own subjective interpretation, and has not been generally accepted within the relevant scientific community. *See Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 311 (2d Cir. 2008) (rejecting expert's conclusory statement where it was not accompanied by "any evidentiary citation" or followed by any elaboration of the expert's reasoning); *Hudgens v. Bell Helicopters/Textron*, 328 F.3d 1329, 1344 (11th Cir. 2003) ("[A]n expert's failure to explain the basis for an important inference mandates exclusion of his or her opinion."). Therefore, Dr. Miklos's unsupported testimony that there are safer alternative products is unreliable and should be excluded.

III. This Court should exclude Dr. Miklos's opinions regarding the adequacy of the TVT Secur IFU and the associated physician training.

Plaintiffs concede that Dr. Miklos will only be offering opinions related to the TVT Secur IFU from a surgeon's clinical perspective. He will not be offering regulatory compliance or legal conclusions regarding the adequacy of the warnings. Nonetheless, certain of his opinions still exceed the bounds of his expertise or are not supported by reliable evidence.

Dr. Miklos opines at length regarding Defendants' failure to train surgeons in the techniques contained in the IFU. Miklos Rep. at 18-19. However, inadequate training is not relevant because he does not identify any requirement that imposes a duty on Defendants to train. He admits that the FDA places the obligation to obtain specialized training on the treating physician. 2/6/15 Dep. at 204:19-24. He agrees that companies like Ethicon sell almost exclusively to hospitals and that it is the hospital credentialing committee's job to make sure doctors are trained to do surgeries before credentials are given. 2/6/15 Dep. at 208:6-209:19. He agrees ultimately that it is the physician's judgment call as to whether he or she is competent and qualified to do the surgery. *Id*. at 209:21-25. He admits that there is no regulatory agency mandating that companies like Ethicon conduct training. *Id*. at 211:11-19. Dr. Miklos's opinion that Ethicon failed to provide adequate training is irrelevant given his admissions that it was not required to in the first place.

Notably, contrary to Plaintiffs' argument that relevancy is not a *Daubert* consideration, Pltfs' Opp. at 15, if an expert's testimony is not relevant, it does not "fit" the case and should be excluded under *Daubert*. Additionally, as this Court has appropriately noted, "[w]hether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct," that are beyond the purview of expert testimony. *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Order at 18 (S.D. W. Va. Nov. 20, 2014)

Moreover, Dr. Miklos does not support his criticism that the IFU fails to adequately warn regarding mesh shrinkage and contraction, foreign body reactions, and vaginal deformation. Miklos Rep. at 20-22. To the contrary, Dr. Miklos believes that mesh bladder sling surgeries "are considered the Gold standard . . . of care for urinary leakage." 2/6/15 Dep. at 128:2-7. He actually prefers Ethicon's Prolene polypropylene mesh (specifically the TVT retropubic device

and more recently the TVT Exact device) and admits that it is the "best tolerated material to date with the least amount of complications." *Id.* at 195:8-12; *see also* 4/8/16 Dep. at 27:16-21; 29:19-30:2 (expressing opinions that TVT retropubic and TVT-O full-length sling are more effective than TVT Secur); *id.* at 12:12-14 (describing current use of TVT Exact and retropubic sling). This is the same mesh used in the TVT Secur. Dr. Miklos does not provide any explanation of why mesh shrinkage and contraction, foreign body reactions, and vaginal deformation are not issues for him with the other TVT products he uses, but are unacceptable in the TVT Secur. His opinion is unreliable and should be excluded.

CONCLUSION

For the reasons set forth above, and in Defendants' opening motion papers, the Court should limit the parameters of Dr. Miklos's testimony consistent with the foregoing.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I William M. Gage, certify that on May 16, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
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